MEMORANDUM

DATE: 8/23/06

FROM: Dr. Andrew C. Von Eschenbach
Acting Commissioner
United States Food and Drug Administration

TO: NDA 21-045, S-011

SUBJECT: Appropriate age restriction for Plan B®

This memorandum regards Barr Laboratories' (Barr or the sponsor[1]) supplemental new drug application (sNDA) dated April 22, 2003, and Barr's subsequent amendments, including its amended sNDA dated August 17, 2006. Barr's most recent sNDA requests that FDA switch Plan B's prescription (Rx) status to non-prescription for women 18 years of age and older, and to have Plan B® remain Rx for girls under 18 years of age.

In an August 26, 2005 memo written by Dr. Steven Galson, the Director of the Center for Drug Evaluation and Research (CDER), CDER found that for women 17 and older the existing Rx dispensing requirements for Plan B® are not necessary to protect the public health and that an Rx-only to non-prescription switch for those consumers is authorized under 21 U.S.C. 353(b)(3) and 21 CFR 310.200. CDER also determined, however, that Barr had not established that Plan B® could be used safely and effectively by young adolescents – girls 16 and younger – for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug. As a result of this scientific conclusion (with which I concur), Plan B® may not lawfully be made available without a prescription to this group under section 503(b) of the Federal Food, Drug, and Cosmetic Act.

In considering the difficulty of enforcing an age-based restriction on the availability of this oral hormonal contraceptive, I have concluded that 18 (rather than 17) is the more appropriate cutoff point to best promote and protect the public health. The state-regulated pharmacies that will be dispensing Plan B® under Barr's voluntary CARE℠ program (as well as society as a whole) are more familiar with 18 as a cutoff age. I understand that in all 50 states, 18 is the age of majority (i.e., the legal delineation between minor and adult), and retail outlets, including pharmacies, are familiar with using 18 as the age restriction for the sale of certain products. With regard to drug products, for example, the legal age to purchase FDA approved non-prescription nicotine replacement therapy products is 18. Moreover, I also understand that as a matter of state law many products routinely sold by pharmacies, e.g., tobacco products and non-prescription cough-cold products like pseudoephedrine, are restricted to consumers 18 and older.

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[1] The current applicant for the Plan B sNDA is Duramed Research Pharmaceuticals (Duramed), a wholly-owned subsidiary of Barr. For ease of reference, this memo will refer to both entities as Barr.

This approach builds on well-established state and private-sector infrastructures to restrict certain products to consumers 18 and older. Indeed, the agency selected 18 as the appropriate age for non-prescription nicotine replacement therapy products, in part, because the States had already uniformly restricted the sale of tobacco products to those 18 and older. By so doing, FDA was able to utilize the existing state-created infrastructure limiting the sale of tobacco products to minors to ensure the enforcement of its age-based restriction on non-prescription nicotine replacement therapy products. Here, Barr's CARE℠ program specifically utilizes state-licensed pharmacies to implement its restricted distribution plan. Given this fact, and the existing experience pharmacies have enforcing the age-based restriction of 18, I have determined that to best protect and promote the public health non-prescription Plan B® should be available for ages 18 and above.

Leveraging well-established state and private-sector infrastructures will allow for comprehensive and effective enforcement of the age-based restrictions. As a result, this approach should minimize the likelihood that younger girls for whom Plan B® has not been found safe and effective for non-prescription use will have access to the product without professional supervision. Therefore, this approach should help ensure safe and effective use of the product.